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### TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER 701039-050025

PLICATION NO. (If known, see 37 CFR 1.5)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED 09 January 2003 (9.01.2003) PCT/US2004/000447 09 January 2004 (9.01.2004) TITLE OF INVENTION METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER APPLICANT(S) FOR DO/EO/US CHILDREN'S MEDICAL CENTER CORPORATION, et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.  $|\mathbf{X}|$ The US has been elected (Article 31). XA copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Other items or information: See Attachment 1

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PTO-1390 (Rev. 02-2005) Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. U.S. APPLICATION NO. (if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO. ATTORNEY'S DOCKET NUMBER PCT/US2004/000447 701039-050025 CALCULATIONS PTO USE ONLY 21. 🔯 Basic national fee......\$300 300.00 22. X Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of 200.00 All other situations.....\$200 Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an 100.00 International Search Report prepared and provided to the Office......\$400 All other situations......\$500 \$ \$ 600.00 TOTAL OF 21, 22 and 23 = Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. **Total Sheets** Extra Sheets Number of each additional 50 or fraction **RATE** thereof (round up to a whole number) -51 <sub>/50 =</sub> 0.00 - 100 = \$ x \$250 Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest \$ claimed priority date (37 CFR 1.492(h)). 130.00 **CLAIMS** NUMBER FILED **NUMBER EXTRA** RATE \$ Total claims - 20 = \$ x \$ 50 4 24 200.00 Independent claims - 3 = \$200 \$ 200.00 4 1 x MULTIPLE DEPENDENT CLAIM(S) (if applicable) \$360 \$ 0.00 **TOTAL OF ABOVE CALCULATIONS =** \$ 1,130.00 Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. 565.00 \$ 565.00 Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest \$ 0.00 claimed priority date (37 CFR 1.492(i)). **TOTAL NATIONAL FEE =** \$ 565.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied 0.00 by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property TOTAL FEES ENCLOSED = 565.00 Amount to be \$ refunded: Amount to be \$ charged: \_\_\_\_ to cover the above fees is enclosed. A check in the amount of \$ Please charge my Deposit Account No. 50-0850 in the amount of \$ 565.00 to cover the above fees. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0850 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: David S. Resnick NIXON PEABODY LLP David S. Resnick 100 Summer Street NAME Boston, MA 02110-2131 US REGISTRATION NUMBER

## JC14 Rec'd PCT/PTO 01 JUL 2005,

#### Practitioner's Docket No. 701039-050025-US

#### **PATENT**

#### IN THE UNITED STATES RECEIVING OFFICE

International Application Number	International Filing Date	International Earliest Priority Date
PCT/US2004/000447	09 January 2004	09 January 2003
	09.01.2004	09.01.2003

TITLE OF INVENTION:

METHODS FOR DIAGNOSIS AND PROGNOSIS OF CANCER

APPLICANTS FOR DO/US:

CHILDREN'S MEDICAL CENTER CORPORATION

INVENTORS FOR DO/US:

ZETTER, Bruce; HUTCHINSON, Lloyd; BAO, Lere

U.S. SERIAL NO.:

TO BE ASSIGNED

## VERIFIED CERTIFICATION OF EXPRESS MAILING DATE (INTERNATIONAL APPLICATION (37 C.F.R. section 1.10(c))

I declare that, on <u>July 1, 2005</u> I deposited, with the United States Postal Service, in an envelope "Express Mail, Post Office to Addressee," bearing Label Number EV 653000627 US, addressed to the U.S. Receiving Office "MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450," and having an express mail certification that I executed, the following papers:

- 1. Transmittal Letter to the U.S. Receiving Office PTO 1390 in duplicate (6 pp.);
- 2. Application Data Sheet (7 pp.);
- 3. Preliminary Amendment (6 pp.);
- 4. Copy Published PCT Cover Sheet WO 2004/063712 A3 (1 pg.);
- 5. Copy Form PCT/IB/308 (Second Notice) (1 pg.);
- 6. Copy Form PCT/ISA/210 & 220 (7 pp.);
- 7. Copy Form PCT/ISA/237 (5 pp.);
- 8. Sequence Listing Statement (3 pp.);
- 9. Sequence Listing Disk 1;
- 10. Sequence Listing Paper Copy (2 pp.);
- 11. Return Receipt Postcard.

A copy of these papers from the file of this application is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: \_July 1, 2005

Nicole M. Aguirre

(type or print name of person certifying)